

REMARKS

Applicants respectfully request entry of the amendment and reconsideration of the claims. Claims 1 and 2 have been cancelled without prejudice or disclaimer. Claims 3, 7, 8, 12-15, 17, and 22-24 have been amended. Claim 3 has been recast in independent form. Certain dependent claims have been amended accordingly to depend from claim 3 rather than claim 1 and/or to recite the expression “GRF analog” for consistency with the amended parent claim from which they depend. After entry of the amendment, claims 3-24, 50-56, and 74-80 will be pending. Applicants submit the amendment is supported throughout the specification and does not introduce new matter.

Restriction Requirement

The Office Action required restriction under 35 U.S.C. § 121 to one of the following groups:

Group I: claims 1-24, drawn to a method of increasing muscle function; and

Group II: claims 50-56 and 74-80, drawn to a composition comprising a growth hormone secretagogue.

Without acquiescing to the statements made in the Restriction Requirement, Applicants elect the claims of Group I for prosecution in the present application with traverse. The elected group encompasses claims 3-24.

Species Election

The Office Action further required an election of species under 35 U.S.C. §121 as follows:

1. A single species among the following conditions: chronic obstructive pulmonary disease, chronic renal failure, congestive heart failure, human immunodeficiency

virus infection, acquired immunodeficiency syndrome, cancer, malnutrition, frailty, immobilization paraplegia and spinal disorder; and

2. A single species among the following administration route: intravenous, oral, transdermal, subcutaneous, mucosal, intramuscular, intranasal, intrapulmonary, parenteral, intrarectal and topical.

Without acquiescing to the statements made in the Restriction Requirement, Applicants elect the following condition with traverse: chronic obstructive pulmonary disease, and the following administration route with traverse: subcutaneous. The elected species of condition encompasses claims 3-24. The elected species of administration route encompasses claims 3-24.

The Examiner acknowledges at page 4 that claims 1-24 are generic to the condition and administration route. Upon indication of allowance of a generic claim, Applicants note they are entitled to search and consideration of additional species which depend from or otherwise require all the limitations of an allowable claims as provided by 37 C.F.R. § 1.141. See MPEP §809.02(a).

The above-noted restriction election and species elections are made with traverse. The present application is a national stage application under 35 U.S.C. 371. In this regard, Applicants respectfully refer to 37 C.F.R. § 1.499, which reads in part as follows:

If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted.

As such, 37 C.F.R. § 1.475, which corresponds to PCT Rule 13, should be followed when considering such issues. As stated in MPEP 1893.03 (d):

Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. 371.

In this regard, Applicants respectfully submit that during the international phase of the corresponding PCT application, the PCT International authorities did not raise any such issues. Indeed, it is indicated in the Written Opinion and the International Preliminary Report on Patentability (copies attached) which issued in the corresponding PCT application that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is complied with (see item 3 of Box No. IV at page 5 of the IPRP and page 4 of the Written Opinion). This inconsistency thus indicates that the relevant PCT criteria which should have been applied, have not been applied in the instant national phase application. In addition, the Examiner has not provided any evidence that supports lack of unity of invention

Further, Applicants respectfully submit that the Examiner has failed to establish that a search of the complete application would be an undue burden as required by MPEP 803. It is Applicants' position that the Examiner has failed to establish that a search of the entire application constitutes an undue burden as the claims in Groups I and II are classified in the same class (514) and subclass (12).

The present elections are made without prejudice or disclaimer as to any non-elected subject matter. Applicant specifically reserves the right to file one or more divisional application(s) directed to non-elected subject matter.

Amendment dated May 4, 2009

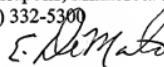
Reply to Restriction Requirement Office Action of February 4, 2009

Conclusion

Favorable consideration is respectfully requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300



Eric E. DeMaster
Reg. No. 55,107
EED:jmm

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